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April 7, 2014

Norm Frederick
Pennsylvania Department of Environmental Protection
Bureau of Air Quality – Title V Section
Northeast Regional Office
2 Public Square
Wilkes-Barre, PA 18711-0790

RE: Donaldson Catalytic Oxidizer Catalyst Replacement
B. Braun Medical Inc. (TVOP 39-00055)

Dear Mr. Frederick:

B. Braun Medical Inc. (B. Braun) operates a surgical and medical instrument apparatus manufacturing facility located at 901 Marcon Blvd. in Allentown, Pennsylvania. The facility currently operates under the Pennsylvania Department of Environmental Protection (PADEP) Title V Operating Permit Number (TVOP) 39-00055.

B. Braun operates an ethylene oxide (ETO) sterilization process and is subject to 40 CFR Part 63, Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities. B. Braun maintains eight (8) ETO sterilization chambers (Units 101 – 108) to sterilize surgical and medical devices. From the sterilization chamber, the sterilized devices are directed to an aeration chamber or room (Unit 110). Potential ETO emissions from both the sterilization chamber and the aeration chamber are vented to control devices. ETO emissions from the sterilization chamber are routed to either the Deoxx wet scrubbing unit or the Donaldson Catalytic Oxidizer (DCO), which utilizes a catalyst in conjunction with oxidation to control ETO emissions. The Deoxx wet scrubbing unit achieves a 99% ETO removal efficiency. The DCO achieves a 99% ETO removal efficiency or maintains an outlet concentration of less than 1 ppmv.

In order to ensure the effectiveness of the catalyst and to maintain the required 99% destruction efficiency and/or 1 ppmv outlet concentration, §63.363(b)(4) provides three (3) work practice options for catalytic oxidizers as provided below:

(4) Facilities with catalytic oxidizers shall comply with one of the following work practices:

> *(i) Once per year after the initial compliance test, conduct a performance test during routine operations, i.e., with product in the chamber using the procedures described in §63.365(b) or (d) as appropriate. If the percent efficiency is less than 99 percent, restore the catalyst as soon as practicable but no later than 180 days after conducting the performance test; or*

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(ii) Once per year after the initial compliance test, analyze ethylene oxide concentration data from §63.364(e) or a continuous emission monitoring system (CEMS) and restore the catalyst as soon as practicable but no later than 180 days after data analysis; or,

(iii) Every 5 years, beginning 5 years after the initial compliance test (or by December 6, 2002, whichever is later), replace the catalyst bed with new catalyst material.

As discussed in B. Braun's March 2009 letter to PADEP, B. Braun last replaced the catalyst bed with new catalyst material in March 2009. In accordance with the work practice standard in 40 CFR §63.363(b)(4)(iii), B. Braun is required to replace the catalyst bed with new catalyst material every five (5) years. B. Braun replaced the catalyst bed with new catalyst material on Monday, March 24, 2014 and maintains records of the replacement onsite. B. Braun plans to continue to comply with this work practice and will replace the catalyst bed with new catalyst material prior to March 24, 2019.

If you have any questions, please do not hesitate to call me at (610) 596-2584.

Sincerely,
B. Braun Medical Inc.

David R. Lauer
Environmental, Health and Safety Manager-PA Operations

cc: Ryan Johnson – B. Braun
Lindsey W. Kroos – ALL4